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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,432	03/14/2001	Ivo Buschmann	0780.0210000/JAG/KRM	3195

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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 09/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/805,432

Applicant(s)

BUSCHMANN ET AL.

Examiner

J. Eric Angell

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,8-13,15-20,22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1,3,4,6,8-13,15-20,22 and 23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1, 3, 4, 6, 8-13, 15-20, 22 and 23 are pending in the application.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 3, 4, 6 and 8-12, drawn to a method for enhancing arteriogenesis comprising contacting organs, tissues or cells with TGF β 1, wherein TGF β 1 is a derivative or a functionally equivalent substance that is an antibody, classified in class 424, subclass 130.1.
 - II. Claims 1, 3, 4, 6 and 8-12, drawn to a method for enhancing arteriogenesis comprising contacting organs, tissues or cells with TGF β 1, wherein TGF β 1 is a derivative or a functionally equivalent substance that is a (poly)peptide, classified in class 514, subclass 2.
 - III. Claims 1, 3, 4, 6 and 8-12, drawn to a method for enhancing arteriogenesis comprising contacting organs, tissues or cells with TGF β 1, wherein TGF β 1 is a derivative or a functionally equivalent substance that is a nucleic acid encoding TGF β 1, classified in class 514, subclass 44.
 - IV. Claims 1, 3, 4, 6 and 8-12, drawn to a method for enhancing arteriogenesis comprising contacting organs, tissues or cells with TGF β 1, wherein TGF β 1 is a derivative or a functionally equivalent substance that is a small organic compound, classified in class 514, subclass 1.

- V. Claims 1, 3, 4, 6 and 8-12, drawn to a method for enhancing arteriogenesis comprising contacting organs, tissues or cells with TGF β 1, wherein TGF β 1 is a derivative or a functionally equivalent substance that is a ligand, classified in class 424, subclass 184.1.
- VI. Claims 1, 3, 4, 6 and 8-12, drawn to a method for enhancing arteriogenesis comprising contacting organs, tissues or cells with TGF β 1, wherein TGF β 1 is a derivative or a functionally equivalent substance that is a hormone, classified in class 514, subclass 359.
- VII. Claims 1, 3, 4, 6 and 8-12, drawn to a method for enhancing arteriogenesis comprising contacting organs, tissues or cells with TGF β 1, wherein TGF β 1 is a derivative or a functionally equivalent substance that is a PNA, classified in class 435, subclass 455.
- VIII. Claims 1, 3, 4, 6 and 8-12, drawn to a method for enhancing arteriogenesis comprising contacting organs, tissues or cells with TGF β 1, wherein TGF β 1 is a derivative or a functionally equivalent substance that is a peptidomimetic, classified in class 514, subclass 9.
- IX. Claims 13 and 15-20, drawn to a method for the treatment of tumors comprising contacting and organ, tissue or cells with an agent which suppresses arteriogenesis wherein the agent is derived from an antibody, classified in class 424, subclass 130.1.
- X. Claims 13 and 15-20, drawn to a method for the treatment of tumors comprising contacting and organ, tissue or cells with an agent which suppresses arteriogenesis

Art Unit: 1635

wherein the agent is derived from a polypeptide, classified in class 514, subclass

2.

- XI. Claims 13 and 15-20, drawn to a method for the treatment of tumors comprising contacting and organ, tissue or cells with an agent which suppresses arteriogenesis wherein the agent is derived from a nucleic acid, classified in class 514, subclass 44.
- XII. Claims 13 and 15-20, drawn to a method for the treatment of tumors comprising contacting and organ, tissue or cells with an agent which suppresses arteriogenesis wherein the agent is derived from small organic compound, classified in class 514, subclass 1.
- XIII. Claims 13 and 15-20, drawn to a method for the treatment of tumors comprising contacting and organ, tissue or cells with an agent which suppresses arteriogenesis wherein the agent is derived from a ligand, classified in class 424, subclass 184.1.
- XIV. Claims 13 and 15-20, drawn to a method for the treatment of tumors comprising contacting and organ, tissue or cells with an agent which suppresses arteriogenesis wherein the agent is derived from a hormone, classified in class 514, subclass 359.
- XV. Claims 13 and 15-20, drawn to a method for the treatment of tumors comprising contacting and organ, tissue or cells with an agent which suppresses arteriogenesis wherein the agent is derived from a PNA, classified in class 435, subclass 455.
- XVI. Claims 13 and 15-20, drawn to a method for the treatment of tumors comprising contacting and organ, tissue or cells with an agent which suppresses arteriogenesis

Art Unit: 1635

wherein the agent is derived from a peptidomimetic, classified in class 514, subclass 9.

XVII. Claims 22 and 23, drawn to a method for enhancing arteriogenesis comprising ex vivo treatment wherein a matter is removed from the patient a nucleic acid is introduced into said matter and then the matter is reintroduced into the subject, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because each Invention is drawn to the administration of a chemically distinct compound such as an antibody, polypeptide, nucleic acid, etc. Therefore, the inventions have different modes of operation and restriction is proper.
3. Inventions IX-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because each Invention is drawn to the ex vivo administration of a chemically distinct compound such as an antibody, polypeptide, nucleic acid, etc. Therefore, the inventions have different modes of operation and restriction is proper.
4. Inventions I-VIII are unrelated to inventions IX-XVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

Art Unit: 1635

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the inventions have different functions and effects. For instance, the function and effect of Inventions I-VIII is to enhance arteriogenesis, while the function and effect of Inventions IX-XVI is to treat tumors by inhibiting arteriogenesis.

5. Inventions IX-XVI are unrelated to Invention XVII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the inventions have different functions and effects. For instance, the function and effect of Inventions IX-XVI is to treat tumors by inhibiting arteriogenesis while the function and effect of Inventions XVII is to enhance arteriogenesis.

6. Inventions I-VIII are unrelated to Invention XVII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions have different modes of operation. For instance, Inventions I-VIII are drawn to the administration of compounds directly to cells, tissues or organs in a subject (in vivo administration of the compounds), while Invention XVII is drawn to the administration of the compounds to cells that are first removed from the subject and then returned to the subject after administration of the compound (ex vivo administration).

Art Unit: 1635

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and because the search required for each Group is distinct, requiring different search strategies and different search terms. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

Art Unit: 1635

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
September 20, 2002



JEFFREY FREDMAN
PRIMARY EXAMINER